

The partnership and Milton Temerson were charged with causing the acts of repacking and dispensing of the drugs involved in each of the 6 counts of the information. In addition, Walker N. Fricks in 1 count, Grafton G. Smith in 1 of the other counts, and James O. Self in 1 of the 2 other counts were charged with causing the acts involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (2), the repackaged *sulfadiazine tablets* failed to bear a label containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged *Donnatal tablets* contained a chemical derivative of barbituric acid, phenobarbital, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged *Donnatal tablets* failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *sulfadiazine tablets* failed to bear a label containing the common or usual name of the drug; Section 502 (e) (2), the repackaged *Donnatal tablets* were fabricated from two or more ingredients, and the label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* failed to bear such adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, as are necessary for the protection of users.

DISPOSITION: January 10, 1952. Pleas of nolo contendere having been entered, the court imposed a fine of \$50 against each of the defendants.

3747. Misbranding of Vitoplus capsules, vitamin A capsules, vitamin B complex capsules, and d-alpha-tocopheryl acetate capsules. U. S. v. 115 Bottles, etc. (F. D. C. No. 32022. Sample Nos. 9902-L, 9903-L, 9905-L to 9907-L, incl.)

LIBEL FILED: November 23, 1951, Northern District of Illinois.

ALLEGED SHIPMENT: On or about August 21, September 21, and October 5, 1951, from Detroit, Mich., by the Gelatin Products Div., R. P. Scherer Corp.

PRODUCT: 115 100-capsule bottles of *Vitoplus capsules*, 1 15,000-capsule box and 49 50-capsule bottles of *vitamin A capsules*, 156 100-capsule bottles of *vitamin B complex capsules*, and 139 100-capsule bottles of *d-alpha-tocopheryl acetate capsules* at Chicago, Ill., together with a number of booklets entitled "Healthway Products Almanac 1951."

RESULTS OF INVESTIGATION: All of the products originally were shipped in bulk, and those products contained in the bottles represented the portions of the products which had been repackaged by the consignee, the Illinois Herb Co., Chicago, Ill. The booklets which are referred to above were printed locally and were to be sent by mail to prospective customers.

LABEL, IN PART: (Bottle) "100 Vitoplus No 59 Capsules Ingredients in each capsule: Liver Desiccated - 200 mg. Ferrous Sulfate, Dried USP - 136.1 Mg. (Equivalent to 40 mg. of iron) Thiamin Hydrochloride USP - 1 mg. Riboflavin USP - 2 mg. A fermentation extract equivalent in microbiological potency to Vitamin B₁₂ - 1 microgram."

(Box) "Quantity 15,000 * * * Ingredients in each capsule * * * Vitamin A 25,000 USP Units."

(Bottle) "50 Soluble Gelatin Vitamin A Capsules Each Capsule Contains: 25,000 USP Units (Fish Liver Oil)."

(Bottle) "No. 190. 100 Capsules Healthway Therapeutic Type B Complex Ingredients in each capsule: Thiamin Hydrochloride USP (Vitamin B₁) 5 mg. Riboflavin USP (Vitamin B₂) 5 mg. Pyridoxine Hydrochloride (Vitamin B₆) 1 mg. Calcium Pantothenate 25 mg. Niacin Amide USP 50 mg. With other B-Complex factors from liver."

(Bottle) "100 No. 709 Vim-EE Capsules Each capsule contains d-alpha Tocopheryl Acetate (from vegetable oils) equivalent by biological assay to 50 International Units Vitamin E."

NATURE OF CHARGE: *Vitoplus capsules*. Misbranding, Section 502 (a), the following statements and design appearing in the accompanying booklet were misleading since the article was not effective for the purposes stated and implied: (Page 15) "Get this 'Red Magic' for Your Blood Building Program [picture of a bottle labeled "Vitoplus Capsules Vitamin B₁₂"] * * * feel full of zest and able to enjoy life to it's fullest measure. If you feel 'all done in' or 'washed out' most of the time, if your days seem to drag along because of that wornout feeling * * * blood that is deficient in red blood cells * * *." Further misbranding, Section 502 (a), the following statements and design in the accompanying booklet were misleading since the need for vitamin B₁₂ in human nutrition has not been established, and any useful properties of it other than in pernicious anemia have not been recognized: (Page 15) "Dynamic Vitamin B₁₂ * * * [picture of a bottle labeled "Vitoplus Capsules Vitamin B₁₂"] the other vitamins do their work quicker and more efficiently * * * dynamic Red Magic Vitamin B₁₂, in the quantity necessary to aid your blood-building program * * *." Further misbranding, Section 502 (a), the statement on the bottle label "Ingredients in each capsule Liver Desiccated - 200 mg. * * *" was misleading since the label of the article failed to reveal the material fact that the amount of dried liver supplied by the article when taken as directed was essentially inconsequential.

Vitamin A capsules. Misbranding, Section 502 (a), the following statements in the booklet accompanying the article were false and misleading since the article was not effective for the purposes stated and implied: (Page 26) "Sinusitis-Head Colds-Catarrh? * * * sinus distress * * * dry skin * * * Lack of energy * * * impairment of teeth and bones * * * Vitamin A Capsules * * *."

Vitamin B complex capsules. Misbranding, Section 502 (a), the following statements in the booklet accompanying the article were false and misleading since the article was not effective for the purposes stated and implied: (Page 26) "Diet for liver disorder * * * supplemented with Vitamin B Complex improved the health of patients with cirrhosis of the liver * * * B Complex group of Vitamins * * * spark the human machine in consuming and using the elements that supply the nerves and system with body building and sustaining fuel * * * No. 190 Vitamin B Complex Capsules * * *." Further misbranding, Section 502 (a), the statement appearing in the accompanying booklet, namely, (page 26) "Every person needs the B Complex Vitamins," was misleading in the absence of a statement of the material fact that the B complex vitamins are normally supplied by the diet. Further mis-

branding, Section 502 (a), the designation "Healthway" appearing on the bottle label was false and misleading since the use of the article would not assure maintenance or restoration of the user's health.

d-alpha-tocopheryl acetate capsules. Misbranding, Section 502 (a), the following statements in the booklet accompanying the article were false and misleading since the article was not effective for the purposes stated and implied: (Page 20) "Value in menopause (change of life) * * * treatment of heart disease * * * preserving tooth enamel * * * prevention of fatty livers * * * protect the body in keeping the Vitamin A reserve up to par * * * betterment in your health * * * No. 709 Vim-EE Capsules * * *."

The articles were alleged to be misbranded in the above respects while held for sale after shipment in interstate commerce.

Vitamin A capsules. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use. The article was misbranded in this respect when introduced into and while in interstate commerce.

The *d-alpha-tocopheryl acetate capsules* were alleged also to be misbranded when introduced into and while in interstate commerce, under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: April 1, 1952. Default decree of condemnation and destruction.

3748. Misbranding of Hope Mineral tablets. U. S. v. 32 Dozen Bottles, etc. (and 26 other seizure actions). (F. D. C. Nos. 32995, 33008 to 33012, incl., 33014, 33015, 33017 to 33019, incl., 33023, 33032, 33037, 33038, 33043, 33045, 33046, 33163, 33171, 33172, 33176, 33178, 33179, 33185, 33186, 33203 to 33206, incl., 33253. Sample Nos. 2109-L, 2110-L, 3841-L to 3843-L, incl., 5095-L, 5097-L, 6446-L, 6447-L, 7317-L, 7318-L, 8731-L, 10197-L, 10198-L, 21925-L, 21927-L, 24915-L, 24921-L, 27009-L, 27221-L, 27224-L to 27226-L, incl., 27530-L, 28197-L, 28198-L, 30522-L, 30523-L, 33706-L, 33707-L, 41973-L, 41974-L, 48408-L.)

LIBELS FILED: Between April 1 and May 29, 1952, District of Massachusetts, Northern District of California, Northern and Western Districts of New York, Western District of Washington, District of Columbia, Western District of Michigan, Western District of Louisiana, Middle District of Pennsylvania, Northern District of Iowa, Eastern District of Virginia, Northern District of Illinois, and Middle District of North Carolina.

ALLEGED SHIPMENT: Between the approximate dates of September 26, 1951, and March 28, 1952, by the Hope Co., from St. Louis, Mo., and East St. Louis, Ill.

PRODUCT: 1,146 dozen bottles of *Hope mineral tablets* at Boston and Springfield, Mass.; Alameda, Oakland, San Francisco, Watsonville, San Mateo, Burlingame, and Sacramento, Calif.; Amsterdam, Schenectady, and Rochester, N. Y.; Seattle, Wash.; Washington, D. C.; Grand Rapids, Mich.; Shreveport, La.; Harrisburg, Pa.; Cedar Rapids, Iowa; Alexandria, Va.; Chicago, Ill.; and Durham and Greensboro, N. C.

RESULTS OF INVESTIGATION: Various representations concerning the conditions for which the product was intended were published in advertisements contained in local newspapers at the places where the product was located. These advertisements were printed on instructions of, and from mats furnished by, the Hope Co.